PHI, INCORPORATED

February 15, 2006

Mr. Kirk D. Sooter, Compliance Branch
Director Food & Drug Administration
Baltimore District Office 6000 Metro Drive,
Suite 101 Baltimore, MD 21215

Dear Mr. Sooter:

This letter is an update of our earlier response to your WARNING LETTER of October 13, 2005 concerning our two products Zcaine and Sonacaine.

After reviewing your letter to us, it was brought to my attention that the DRLS Official Correspondent for us had inadvertently sent to your office older labels that are no longer being used for Sonacaine and labels for Zcaine that were never put in use, but was prior labeling that had been changed before the first distribution. Our Correspondent subsequently resubmitted Form 2657 to FDA on October 19, 2005 to correct this error.

In our October 24, 2005 response we submitted corrective actions for all of the items in your warning letter. Our corrective actions are summarized below:

1. Submitted to the FDA proposed revised labeling for Sonacaine which removes all references to the practice of "wrapping', "occluding" or covering with plastic wrap".
2. Submitted to the FDA current Zcaine labeling which contains no references to the practice of "wrapping', "occluding" or covering with plastic wrap".
3. Removed from the Zcaine website all references to the practice of "wrapping', "occluding" or covering with plastic wrap".
4. Corrected the labeling error that identified PHI as the manufacturer (rather than a distributor) of Sonacaine,

In this letter we are responding that we have taken further corrective actions with respect to future labeling of both Sonacaine and Zcaine, to make sure there is absolutely no question of our fullest cooperation and intent to market products that are in complete conformance as an Over-The-Counter Drug Products, and not misbranded.

We have now submitted to you labeling revisions that are in strictest conformance with the labeling found in the External Analgesic Tentative Final Monograph (FR.Vol 8, No., 27, Feb 8, 1983, Page 28.).

http://www.fda.gov/cder/otcmonographs/External_Analgesic/ext_analgesic_TF_PR_19830208.pdf



1025 EXECUTIVE BOULEVARD SUITE 112 CHESAPEAKE, VA 23320

Phone 757-436-4774 Fax 757-549-2753

All labeling for Zcaine and Sonacaine has now been redesigned to contain no references to laser hair removal or other aesthetic procedures that might promote or indirectly imply a "new intended use" or a nonmonograph condition for our 4% lidocaine products. These proposed labels for Sonacaine tube and carton were submitted to your office electronically on February 4,2006, and are appended to this letter These Zcaine tottle and carton labeling were submitted to your office on February 6,2006, and are appended to this letter. Revisions to the Zcaine website were posted to the web at www.Creativeinc.biz on February 15, 2006. The revised website copy is also appended to this letter. We feel, that by ow continuing actions described in this communication, we are meeting or exceeding both the letter of the law and the spirit of the regulation. PHI is making every effort to comply with FDA directives and is committed to offering for sale safe and effective **OTC** products. We again apologize most humbly for any errors that were made, and appreciate your assistance in resolving this matter.

Sincerely,
/s/
Dennis R. Jones, President
Professional Hair Institute, Inc.